

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
CIVIL DIVISION

DEVIN FILIPPELLI, as
Personal Representative of the
ESTATE OF KRYSTAL TALAVERA,
on behalf of the Estate and her
Survivors,

Plaintiff,

vs.

GROW, LLC (d/b/a KD INCORPORATED
and THE KRATOM DISTRO); and
SEAN MICHAEL HARDER, individually.

Defendants.

CASE NO: 9:22cv81731

**AMENDED COMPLAINT FOR WRONGFUL DEATH
AND DEMAND FOR JURY TRIAL**

I. INTRODUCTION

This is a product liability action against the manufacturers, distributors, and sellers of Kratom, a non-prescription dietary supplement. Plaintiff, DEVIN FILIPPELLI, as Personal Representative of THE ESTATE OF KRYSTAL TALAVERA and on behalf of her Estate and her survivors, sues Defendants, GROW, LLC (d/b/a KD INCORPORATED and THE KRATOM DISTRO); and SEAN MICHAEL HARDER (hereinafter jointly “Defendants”), and alleges as follows:

II. STATEMENT OF PARTIES

1. The ESTATE OF KRYSTAL TALAVERA (hereinafter “the Estate”) has been opened in a probate action by the Circuit Court of Palm Beach County.

2. Krystal Talavera (hereinafter “Krystal”) was the mother to four (4) children, all of whom reside in Palm Beach County, Florida.

3. DEVIN FILIPPELLI (hereinafter “Devin”), the eldest of Krystal’s four (4) children, was duly appointed by the Palm Beach County Probate Court as Personal Representative of the Estate. (See Letters of Administration, attached as Exhibit “A”).

4. Devin was and is a resident of the state of Florida. He brings this claim on behalf of the Estate and its beneficiaries, which includes himself and his younger siblings, Krystal’s surviving minor children.

5. Krystal’s children include Devin Filippelli, J. C. F. (a minor), B. B. F. (a minor), and D. G. V. (a minor).

6. Defendant GROW, LLC (d/b/a KD INCORPORATED and THE KRATOM DISTRO) (hereinafter “GROW, LLC”) is a foreign corporation existing and doing business pursuant to the laws of the state of Idaho, with its principal place of business in Boise, Idaho. GROW, LLC was and is an Idaho corporation engaged in the marketing, sale, and distribution of Kratom products to consumers nationwide, including consumers in Palm Beach County, Florida. At all times material and relevant, GROW, LLC did and continues to do business in the state of Florida.

7. Defendant SEAN MICHAEL HARDER (hereinafter “HARDER”) is the registered agent, owner, and operator of GROW, LLC. At all times material and relevant, HARDER resided in, and continues to reside in, Meridian, Idaho. HARDER packaged, shipped, and distributed Kratom products to Krystal directly from his

home in Idaho. HARDER directly accepted payment for and has profited from the importation, distribution, marketing, and sale of GROW, LLC's Kratom products.

8. At all times material and relevant, each Defendant was and is the alter ego of the other.

9. At all times material and relevant, each Defendant conducted business in the state of Florida and did in fact market, distribute, and supply Kratom products to consumers within the state of Florida, including Krystal Talavera.

III. JURISDICTION AND VENUE

10. This action is for damages in excess of seventy-five thousand dollars (\$75,000.00), exclusive of interest, costs, attorneys' fees, and declaratory relief. 28 U.S.C. § 1332(a).

11. The U.S. District Court for the Southern District of Florida has subject matter jurisdiction over this case because it satisfies the requirements of 28 U.S.C § 1332, such that the matter can be heard on the basis of diversity jurisdiction.

12. Defendant GROW, LLC is a limited liability company with citizenship in Idaho. Defendant SEAN HARDER is the only member of GROW, LLC. Defendant SEAN HARDER is domiciled in Meridian, Idaho. Plaintiff is domiciled in Boynton Beach, Florida. There is complete diversity of the parties.

13. Venue is proper in the U.S. District Court for the Southern District of Florida. 28 U.S.C. § 1391.

14. At all times relevant and material, Plaintiff's injuries and causes of action accrued in Palm Beach County, Florida. Additionally, Palm Beach County,

Florida, is where each Defendant continuously transacts business and continuously committed torts upon which Plaintiff's claims are based.

IV. STATEMENT OF FACTS

A. Kratom is a deadly drug that is being marketed as a safe dietary supplement in the United States.

15. Kratom is an herbal extract derived from the leaves of *Mitragyna speciosa*, a tropical tree native to Southeast Asia.

16. The nature and extent of Kratom's impact upon human physiology is the topic of ongoing study.

17. Although not formally classified as an opiate, Kratom contains dozens of psychoactive compounds or alkaloids, many of which are not understood.

18. The two (2) most-studied alkaloids are mitragynine and 7-hydroxymitragynine. These two alkaloids bind to the same opioid brain receptors as morphine. Like opiates, these compounds can lead to analgesia (release of pain), euphoria, and sedation.

19. Kratom's serious health risks include abuse, dependence, addiction, overdose, and death.¹ Scientific literature documents serious concerns regarding the toxicity of Kratom in multiple organ systems. Consumption of Kratom can lead to many adverse health impacts, including respiratory depression, nervousness, agitation, aggression, sleeplessness, hallucinations, delusions, tremors, loss of libido,

¹ See FDA News Release, FDA issues warnings to companies selling illegal, unapproved kratom drug products (<https://www.fda.gov/news-events/press-announcements/fda-issues-warnings-companies-selling-illegal-unapproved-kratom-drug-products-marketed-opioid>) (last accessed Nov. 1, 2022); see also DOJ DEA Drug Fact Sheet – Kratom (https://www.dea.gov/sites/default/files/2020-06/Kratom-2020_0.pdf) (last accessed Nov. 1, 2022).

constipation, skin hyperpigmentation, nausea, vomiting, severe withdrawal, seizures, psychosis, and lung damage.

20. Kratom is not approved for medical purposes, and Kratom is illegal in several states and cities, including: Alabama, Arkansas, Indiana, Rhode Island, Vermont, Wisconsin; San Diego, California; Denver, Colorado; Sarasota County, Florida; Jerseyville, Illinois; and Union County, Mississippi.

21. Kratom is not FDA approved. The FDA issued numerous warnings against the use of products containing Kratom or its psychoactive compounds and has taken action against those who illegally sell the product for pain treatment and other medical uses.²

22. Kratom is not approved for importation and distribution in interstate commerce without a premarket substantiation that the product containing Kratom is reasonably safe for human consumption. The FDA has issued numerous warnings to companies importing and selling Kratom for human consumption and for medicinal purposes. Federal officials have also pursued enforcement actions against those illegally importing and selling adulterated and misbranded products.

23. Nonetheless, products containing Kratom are sold online and at numerous retail outlets throughout the country, including gas stations, vape shops, and head shops.

² See FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA advisory about deadly risks associated with Kratom (<https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fda-advisory-about-deadly-risks-associated-kratom>) (last accessed Nov. 1, 2022).

24. Companies and individuals that produce and sell Kratom, including GROW, LLC and HARDER, present Kratom as an all-natural supplement which is safe for consumption and legal to sell in the United States.

25. By sidestepping consumer protections, the Kratom industry has grown dramatically in the United States. This profitable black-market industry has generated enough ill-gotten gains to fund the development of trade organizations like the American Kratom Association (AKA) and has mobilized lobbyists, a network of Kratom advocates, and industry-backed researchers to try and legitimize the ongoing profiteering of those in the Kratom business, despite their ongoing failure and refusal to comply with the clear and mandatory standards for establishing safety and efficacy of new dietary ingredients, supplements, and drugs before they are sold to the public.

26. With the proliferation of Kratom products, U.S. consumers are paying a heavy price, including a growing number of deaths caused by Kratom.

27. The deceptive marketing and sale of these products encourages consumers to experiment with mysterious and dangerous compounds in lieu of seeking appropriate and approved medical treatments that can be safely supervised by medical professionals.

28. In recent years, several Kratom manufacturers, including Defendants, GROW, LLC and HARDER, began importing, producing, and marketing concentrated Kratom, in capsule and powdered form.

29. Defendants, GROW, LLC and HARDER, misrepresented and misled consumers about the risks of Kratom, and this led to the tragic death of Krystal

Talavera. (See Kratom Distro, Kratom Strain Information guide attached hereto as Exhibit "B").

B. Krystal Talavera suffered a preventable and untimely death caused by Kratom.

30. This case is about the unnecessary death of Krystal Talavera; a death that could have and should have been prevented.

31. On June 20, 2021, thirty-nine (39) year old Krystal Talavera resided in Palm Beach County, Florida, with her partner and children.

32. Just one day prior to her death, on June 19, 2021, Krystal celebrated the high school graduation of her eldest son, Devin Filippelli, who was preparing to attend the University of Florida, to pursue a bachelor's degree in computer science.

33. Krystal was a loving mother for whom family meant everything.

34. Krystal also enjoyed a successful career as a registered nurse at Trustbridge Hospice Care in West Palm Beach, Florida, where she had recently been promoted to manager just prior to her death.

35. In the years preceding Krystal's death, she was introduced to Kratom by friends. Krystal was under the belief that Kratom was, as it is marketed, a safe and natural dietary supplement.

36. Krystal regularly purchased Kratom online from Defendants, GROW, LLC and HARDER, who market Kratom using the name, THE KRATOM DISTRO, and sell various name brands which include "Space Dust," "Green Maeng Da" (a/k/a "G2"), "Green Horned Maeng Da" (a/k/a "G4"), and "Green Riau" (a/k/a "G5"). All four

(4) brands were packaged in Idaho by Defendants, GROW, LLC and HARDER, and shipped to Krystal's home in Boynton Beach, Florida.

37. Krystal regularly purchased and consumed "Space Dust," "Green Maeng Da," "Green Horned Maeng Da," and "Green Riau" Kratom from Defendants, GROW, LLC and HARDER, under the belief that Kratom was a safe dietary supplement with several health benefits.

38. On the morning of June 20, 2021, Krystal was home preparing Father's Day breakfast for Biagio Vultaggio, her partner and father of her youngest child, D.G.V.

39. Around 1100 hours, Mr. Vultaggio woke up, walked out of his bedroom, and found Krystal lying face down on the living room floor.

40. Mr. Vultaggio turned Krystal over, and immediately realized that something was wrong.

41. Krystal's minor child, D.G.V., was present nearby, and witnessed his mother lying on the floor unconscious.

42. Next to Krystal, Mr. Vultaggio found a cup of hot coffee and an open bag of "Space Dust" that Krystal purchased from Defendants, GROW, LLC and HARDER.

43. Mr. Vultaggio called the paramedics and, shortly thereafter, the paramedics arrived and transported Krystal to Bethesda Hospital East in Boynton Beach, Florida.

44. At the hospital, medical personnel pronounced Krystal dead.

45. An autopsy was performed, and the Palm Beach County Coroner determined the cause of death was “acute mitragynine intoxication. At high concentrations, mitragynine produces opioid-like effects, such as respiratory failure.”

46. Plaintiff brings this lawsuit within two (2) years of decedent’s date of death.

V. DAMAGES AND CAUSES OF ACTION

47. The injuries from the dangerous and defective Kratom products that killed Krystal caused and will continue to cause economic losses to the Estate in the form of medical expenses, funeral expenses, lost wages, and loss of earning capacity, in an amount to be determined by a jury.

48. Krystal’s death caused and continues to cause Plaintiff’s beneficiaries and the Estate non-economic damages, including pain and suffering, loss of support and services, and loss of parental companionship, instruction, and guidance, for mental pain and suffering in an amount to be determined by a jury.

49. Krystal suffered an untimely death as a direct and proximate result of the Kratom products that were manufactured, marketed, distributed, and sold by Defendants, GROW, LLC and HARDER.

50. The Estate and its beneficiaries have incurred and will continue to incur enormous general and special damages in an amount to be determined by a jury.

51. Defendants, GROW, LLC and HARDER, are jointly and severally liable for the damages caused to the Estate and its beneficiaries.

COUNT ONE – GROW, LLC AND SEAN MICHAEL HARDER
(STRICT LIABILITY FAILURE TO WARN PURSUANT TO THE
RESTATEMENT SECOND OF TORTS § 402A)

52. GROW, LLC and HARDER were engaged in the business of promoting, manufacturing, distributing, and selling various Kratom products, including those that caused Krystal's ultimate passing, such as the concentrated "Space Dust" discovered nearby Krystal at the time of her death.

53. The Kratom products that Krystal purchased and ingested were expected to and did reach Krystal without substantial change in condition at the time they left Defendants' hands.

54. GROW, LLC's and HARDER's Kratom products were constantly sold without any warning regarding instructions for use, the recommended dosage, and known risks of the products, including the risks of abuse, dependence, addiction, overdose, and death. (Pictures of the Kratom sold to Krystal by Defendants, GROW, LLC and HARDER, are shown on page 22).

55. An ordinary consumer would reasonably conclude that GROW, LLC's and HARDER's Kratom products are unreasonably unsafe when sold without warnings or instructions about the serious adverse health risks, including the risk of overdose and death suffered by Krystal.

56. In addition, at the time of manufacture, the likelihood that GROW, LLC's and HARDER's Kratom products would cause the serious harms inflicted on Krystal rendered GROW, LLC's and HARDER's lack of warnings and instructions completely inadequate.

57. At the time and on the occasion in question, Krystal used GROW, LLC's and HARDER's Kratom products for the very purposes intended and promoted.

58. Without proper warnings and instructions, the Kratom products were unreasonably dangerous, unfit for their intended use, and highly dangerous and defective.

59. If the products had been sold with appropriate warnings and instructions regarding health risks, including but not limited to the risks of overdose and death, then Krystal's overdose and death from Kratom would not have occurred.

60. GROW, LLC and HARDER are strictly liable for all damages caused by their failure to provide adequate warnings and instructions that would have prevented the death caused by their defective and unreasonably dangerous nature of their Kratom products.

61. GROW, LLC and HARDER are liable for all damages caused by their negligent failure to provide adequate warnings and instructions that would have prevented the death caused by their defective and unreasonably dangerous nature of their Kratom products.

62. GROW, LLC and HARDER also had a continuing, post-sale duty to warn regarding the unreasonable risk of harm associated with the Kratom products after the Kratom products had been distributed to Krystal.

63. After Krystal began purchasing and ingesting the Kratom products, GROW, LLC and HARDER received increasing actual and constructive notice about

specific risks and dangers associated with the Kratom products, including the risk of death.

64. After Krystal began purchasing and ingesting the Kratom products, GROW, LLC and HARDER breached their duty to issue adequate post-sale instructions and warnings to reduce and prevent the foreseeable risk of harm and death to Krystal from GROW, LLC's and HARDER's Kratom products.

65. GROW, LLC and HARDER failed to exercise reasonable care to provide adequate post-sale instructions and warnings to Krystal and other Florida residents about the serious health risks and dangers of the Kratom products, including the risk and danger of death.

66. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in Defendants' Kratom products, particularly "Space Dust," "Green Maeng Da," "Green Horned Maeng Da," and "Green Riau," Krystal Talavera overdosed and died, causing irreparable injury and damages to the ESTATE OF KRYSTAL TALAVERA as described herein.

COUNT TWO – GROW, LLC AND SEAN MICHAEL HARDER
(STRICT LIABILITY DESIGN AND MANUFACTURING DEFECT
PURSUANT TO THE RESTATEMENT SECOND OF TORTS § 402A)

67. At the time GROW, LLC and HARDER manufactured the "Space Dust," "Green Maeng Da," "Green Horned Maeng Da," and "Green Riau" Kratom sold to and consumed by Krystal, the products were not reasonably safe as designed.

68. Under a Risk-Utility analysis, the likelihood that the Kratom products would cause Krystal harm, and the seriousness of those harms (including death),

outweighed Defendants' burden to design Kratom products that would have prevented those harms and adverse effects.

69. Under a Consumer Expectation analysis, the Kratom products were more dangerous than the ordinary consumer would reasonably expect, considering the products' intrinsic nature, relative cost, severity of potential harm (including death), lack of warning, recommended dosage, and the cost and feasibility of minimizing such risk.

70. GROW, LLC's and HARDER's Kratom products that were sold to and consumed by Krystal also contained manufacturing defects. "Space Dust," "Green Maeng Da," "Green Horned Maeng Da," and "Green Riau" manufactured by GROW, LLC and HARDER departed from their intended design in that the products were adulterated and/or did not conform to the safe design and purity standards required and specified by Defendants.

71. GROW, LLC and HARDER were aware that they were unable to adequately conform the manufacturing process to achieve products that were reasonably safe for human consumption.

72. The Kratom products, "Space Dust," "Green Maeng Da," "Green Horned Maeng Da," and "Green Riau," sold to Krystal were unreasonably dangerous beyond the expectations of the ordinary consumer and were unfit for their intended use.

73. At the time and on the occasion in question, Defendants' Kratom products, "Space Dust," "Green Maeng Da," "Green Horned Maeng Da," and "Green

Riau,” were being used by Krystal for the purpose for which they were marketed and intended, and the products were defective, unsafe, and unreasonably dangerous.

74. As a direct and proximate result of the defects in Defendants’ Kratom products, Krystal Talavera overdosed and died, causing irreparable injury and damages to the ESTATE OF KRYSTAL TALAVERA as described herein.

COUNT THREE – GROW, LLC AND SEAN MICHAEL HARDER
(BREACH OF WARRANTY PURSUANT TO FLA. STATE. §§ 672.313; 672.314;
& 672.315.)

75. Defendants, GROW, LLC and HARDER, expressly and impliedly warranted that their Kratom products were reasonably fit for their intended purposes of improving health and well-being and as safe dietary supplements.

76. GROW, LLC and HARDER warranted, without limitation, that their Kratom products were completely safe and natural.

77. GROW, LLC and HARDER also warranted that their Kratom products conformed with the express representations contained in Exhibit B.

78. GROW, LLC and HARDER issued these warranties to develop and promote the sale of their Kratom products through their distribution chain, including the sales to Krystal.

79. Defendants GROW, LLC and HARDER’s warranties related to material facts regarding the safety and efficacy of their Kratom products.

80. Defendants GROW, LLC and HARDER’s warranties were part of the basis of the bargain for Krystal’s purchase of their Kratom products.

81. Defendants GROW, LLC and HARDER’s warranties were untrue. Their Kratom products did not conform to the representations that were made.

82. Defendants, GROW, LLC and HARDER, were at all times relevant hereto in privity with Krystal Talavera.

83. As a direct and proximate result of the breach of Defendants' warranties of "Space Dust," "Green Maeng Da," "Green Horned Maeng Da," and "Green Riau" Kratom products, Krystal Talavera overdosed and died, causing irreparable injury and damages to the ESTATE OF KRYSTAL TALAVERA as described herein.

COUNT FOUR – GROW, LLC AND SEAN MICHAEL HARDER
(FRAUDULENT MISREPRESENTATION)

84. Defendants, GROW, LLC and HARDER, made misrepresentations of material facts about their Kratom products and intentionally concealed information about the products from Krystal during the time she bought and used the products.

85. Defendants, GROW, LLC and HARDER, refer to their Kratom products as very effective pain relievers, energy boosters, and a sense of euphoria. (Refer to Exhibit "B" for the complete list of Kratom Strain information).

86. Defendants, GROW, LLC and HARDER, failed in their duty to disclose known material facts to Plaintiff regarding "Space Dust," "Green Maeng Da," "Green Horned Maeng Da," and "Green Riau" Kratom products, including but not limited to:

- a. The health risks associated with regular consumption of Kratom products.
- b. Information regarding adverse events associated with Kratom products.
- c. The risk of addiction, overdose, and death associated with Kratom products.

87. Additional misrepresentations and concealment included, but were not limited to:

- a. Failing to disclose that Kratom products will cause death.
- b. Falsely representing that Kratom products are completely safe and natural.
- c. Falsely representing that their Kratom products are lab tested for quality and purity.

88. The above representations and omissions made by Defendants, GROW, LLC and HARDER, were material and were made with the intent to persuade and induce Krystal to regularly consume their Kratom products.

89. Defendants, GROW, LLC and HARDER, made the above representations or omissions knowing them to be false misrepresentations, or Defendants were ignorant of the truth of the assertions.

90. The above representations and omissions are reflected in GROW, LLC's and HARDER's system for marketing their products. Together, Defendants, GROW, LLC and HARDER, unlawfully promoted and sold the unreasonably dangerous Kratom products to Florida residents, including Krystal Talavera.

91. Defendants, GROW, LLC and HARDER, made the above misrepresentations or omissions with the intention and knowledge that consumers would select the Kratom products for regular consumption for the purposes identified in their marketing.

92. Krystal relied upon and was induced to act in reliance on Defendants GROW, LLC and HARDER's misrepresentations and omissions when she in fact purchased the Kratom products under the assumption that the products were safe and completely natural dietary supplements.

93. As a direct and proximate result of the breach of the warranty regarding the Kratom products, Krystal Talavera overdosed and died, causing irreparable injury and damages to the ESTATE OF KRYSTAL TALAVERA as described herein.

COUNT FIVE – GROW, LLC AND SEAN MICHAEL HARDER
(NEGLIGENCE)

94. As manufacturers, distributors, and sellers of Kratom, GROW, LLC and HARDER had a duty to reasonably investigate and inspect these Kratom products before selling them, to ensure they were safe for human consumption. Defendants also had a duty to ensure that their Kratom products being sold were not adulterated or misbranded, and a duty to ensure their Kratom products did not contain false representations of material facts.

95. When Defendants, GROW, LLC and HARDER, sold their Kratom products to Krystal, Defendants knew or should have known that their Kratom products were not FDA approved and were unreasonably dangerous for human consumption. Knowledge of Kratom's dangers was readily available from news articles, news segments, medical literature, FDA, and the American Kratom Association.

96. Defendants, GROW, LLC and HARDER, packaged and shipped Kratom products to consumers, including Krystal Talavera, directly from HARDER's residence in Meridian, Idaho.

97. Defendants, GROW, LLC and HARDER, knew or should have known that the Kratom products packaged, shipped, and sold from HARDER's home in Meridian, Idaho, were adulterated, misbranded, lacked warning labels, dosage instructions, and carried serious risks of injury and death to consumers, including Krystal Talavera.

98. Defendants, GROW, LLC and HARDER, breached their duties of care in selling Kratom products in one or more of the following ways:

a. Defendants knew of or should have known of Kratom's potential to cause serious side effects, including tolerance, addiction, overdose, and death.

b. Defendants knew or should have known that they were unlawfully selling Kratom products to customers even though the unreasonable health risks of such use were not properly understood, identified, disclosed, approved, or regulated.

c. Defendants knew or should have known that their disclaimers were a sham attempt to avoid responsibility for Kratom products that were not safe for human consumption.

d. Defendants negligently passed on to consumers, including Krystal Talavera, representations about the Kratom products, including

representations that the Kratom was safe, pure, and appropriate for pain relief.

99. GROW, LLC's and HARDER's negligence was a substantial contributing factor and proximate cause of Krystal's death, warranting an award for damages to Plaintiff, the ESTATE OF KRYSTAL TALAVERA.

COUNT SIX – GROW, LLC AND SEAN MICHAEL HARDER
(NEGLIGENCE PER SE PURSUANT TO VIOLATIONS OF THE FOOD,
DRUG, AND COSMETICS ACT AND DIETARY SUPPLEMENT HEALTH
AND EDUCATION ACT)

100. Defendants, GROW, LLC and HARDER, market, sell, and distribute dietary supplements containing *mitragyna speciosa* (a/k/a Kratom), in powder, liquid, and capsule form.

101. As a plant, Kratom is botanical and, therefore, a dietary ingredient within the meaning of 21 U.S.C. § 321(ff)(1)(C).

102. Kratom was not marketed as a dietary ingredient in the United States prior to October 15, 1994; therefore, it is a new dietary ingredient within the meaning of 21 U.S.C. § 350b(d).

103. The Federal Food, Drug, and Cosmetic Act ("FDCA") and the Dietary Supplement Health and Education Act (DSHEA) require manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" to prepare and submit a Premarket Notification to the FDA about these ingredients.³

³ See New Dietary Ingredients (NDI) Notification Process (<https://www.fda.gov/food/dietary-supplements/new-dietary-ingredients-ndi-notification-process> accessed Nov. 1, 2022).

104. Products containing Kratom are deemed adulterated unless the manufacturer or distributor has complied with the mandate of 21 U.S.C. § 350b(a)(2).

105. This mandate requires (1) a premarket substantiation that the Kratom product is reasonably expected to be safe; and (2) a premarket NDI Notification that properly documents the evidence that the Kratom product is reasonably expected to be safe.

106. Furthermore, pursuant to 21 U.S.C. § 331, the following are prohibited acts under the FDCA:

a. The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

b. The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

c. The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise....

d. The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

21 U.S.C. § 331.

107. According to the FDCA, a food shall be deemed misbranded if “(1) its labeling is false or misleading in any particular, or (2)...its advertising is false or

misleading in a material respect or is in violation of Section 350(b)(2)⁴ of this title.”
21 U.S.C. § 343(a).

108. A food is deemed misbranded if in package form unless it bears a label containing “(1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.” 21 U.S.C. § 343(e).

109. Defendants, GROW, LLC and HARDER, violated all above-referenced statutes by failing to notify the FDA of Kratom’s ingredients before marketing and placing Kratom products into interstate commerce, by failing to undergo premarket substantiation to establish that Kratom is reasonably expected to be safe, and mislabeling and misbranding their Kratom products.

110. The Kratom products delivered to Krystal Talavera from Defendants, GROW, LLC and HARDER, display the names, “Space Dust,” “G2,” “G4,” and “G5,” handwritten with a permanent marker as depicted below.

⁴ 21 U.S.C. § 350(b)(2): The labeling for any food to which this section applies may not list its ingredients which are not dietary supplement ingredients described in section 321(ff) of this title (i) except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 343 of this title. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.



111. Moreover, GROW, LLC and HARDER advertise their strains of Kratom to: treat pains and other discomforts; have a euphoric effect; and provide relaxation and energy.⁵

112. The statutory standards mentioned above are designed to protect consumers like Krystal Talavera from the very harms she ultimately suffered, including adverse health impacts, toxicity, and death from an unsafe product.

113. Krystal Talavera is a member of the class that the statute is intended to protect: consumers of dietary supplements in the marketplace.

114. Defendants GROW, LLC and HARDER's violations of these federal statutory standards constitute negligence per se, warranting an award of damages against all Defendants.

CLAIMS FOR DAMAGES COMMON TO ALL COUNTS
CLAIM OF PERSONAL REPRESENTATIVE ON BEHALF OF THE
ESTATE AND SURVIVORS

115. As a direct and proximate result of the negligence and misrepresentations of Defendants which caused the untimely death of Krystal Talavera, the personal representative of her estate sets forth the forgoing claims for the decedent's estate and the decedent's surviving children pursuant to Florida Statutes § 768.21 and § 46.021.

⁵See Kratom Strain Information advertised, marketed, and promoted by Defendants, GROW and HARDER at: (<https://www.kratomdistro.com/strains/>) (last accessed Nov. 1, 2022) and attached hereto as Exhibit B.

**CLAIM OF PERSONAL REPRESENTATIVE ON BEHALF OF THE
ESTATE OF KRYSTAL TALAVERA**

116. The ESTATE OF KRYSTAL TALAVERA has in the past suffered and will in the future continue to suffer the following damages:

a. Loss of earnings of Krystal Talavera from the date of death, including loss of support and services and including contributions in kind with interest;

b. Medical or funeral expenses, or both, that have been incurred due to the death of Krystal Talavera, which have become a charge against her estate and were paid by or on behalf of the decedent.

**CLAIM OF PERSONAL REPRESENTATIVE ON BEHALF OF
SURVIVING CHILDREN**

117. Devin Filippelli, J. C. F. (a minor), B. B. F. (a minor), and D. G. V. (a minor), as the surviving children of Krystal Talavera, have in the past suffered, and will in the future continue to suffer, the following damages:

a. Loss of future support and services from the date of Krystal Talavera's death, with interest;

b. Loss of parental companionship, instruction, guidance, and for mental pain and suffering from the date of death.

VI. PRAYER FOR RELIEF AND DEMAND FOR JURY TRIAL

WHEREFORE, the ESTATE OF KRYSTAL TALAVERA, by and through Krystal's eldest son, DEVIN FILIPPELLI, and on behalf of all its beneficiaries, respectfully requests:

(a) A jury be impaneled to hear this case;

- (b) Judgment against Defendants, GROW, LLC and SEAN MICHAEL HARDER, for wrongful death, general and special damages in an amount to be proven at trial;
- (c) Reasonable attorney's fees and costs; and
- (d) Such other relief as the Court deems just and proper under the circumstances of this case.

Dated: November 11, 2022

Respectfully submitted,



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